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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/873,505
Filing Date: June 04, 2001
Appellant(s): CAO ET AL.

DAVID LECROY
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 22, 2005 appealing from the Office action mailed August 25, 2004.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

A substantially correct copy of appealed claims 26-48 appears on pages 1-4 of the Appendix to the appellant's brief. The minor formality errors are as follows: the subheading of claims 39 and 46 had been deleted from the previous claim amendment filed on January 11, 2005.

(8) Evidence Relied Upon

| | | |
|--------------|------------------|---------|
| 5676994 | ESKINS ET AL. | 10-1997 |
| 6,340,527 B1 | VAN SOEST ET AL. | 01-2002 |
| 6,261,543 B1 | FLETCHER ET AL. | 07-2001 |
| 6,362,146 B1 | MACAULAY | 03-2002 |

Goldemberg, R. SCC Seminar, Drug & Cosmetic Industry, August 1996. Vol. 159, Iss. 2, page 50.

Ashley, L. "Sunburn and Sunscreen Preparations", Poucher's Perfumes, Cosmetics and Soaps, 1993, Chapman & Hall, (9th ed. Hilda Butler), vol. 3, pp. 431-437.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 32-35, 39-42, and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eskins et al. (US 5676994) ("Eskins") in view of Van Soest (US 6340527 B1), Fletcher et al. (U.S. Pat. No. 6,261,543 B1) ("Fletcher"), and Goldemberg (SCC Seminar, Drug & Cosmetic Industry, 1996).

Claimed invention is a surfactant-free aqueous composition comprising "cationic starch encapsulated hydrophobic material" containing an active ingredient. The starch encapsulated hydrophobic material is said to be non-separable.

Eskins teaches non-separable starch-oil compositions useful for food, agriculture, or pharmaceutical and cosmetic carriers or vehicles, which meets the "starch

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encapsulated hydrophobic material" limitation. See col. 13, lines 55 – 63; col. 11, lines 60-66; instant claims 32, 39, 46. The abstract teaches that the composition is prepared in the absence of external emulsifying or dispersing agents. The reference teaches "the presence of the oil component in [the starch-water-oil] composition causes them to function as emulsifying and dispersing agents and makes them receptive to the addition of a variety of water-immiscible materials, for example, additional lipid, volatile, and essential oils and food flavoring materials, antioxidants, medicinal agents, agricultural chemicals". See col. 5, lines 40 – 53. The application of the starch-encapsulated actives in cosmetic formulations includes body and hand lotions, cream, and suntan lotion. Examples also illustrate encapsulating soybean oil. See instant claims 39 and 47. Example 13 teaches a dispersion of 300 g of soybean oil in 3 liters of water, which constitutes 10 % by weight. See instant claims 35, and 42. The method of topically applying the topical composition is an obvious use of the composition. See instant claims 46-48.

It is noted that claims 34, 41 and 48 are product-by-process claims, where only the limitation to the composition itself is given patentable weight. See MPEP § 2113. Eskins nonetheless teaches that the invention is prepared by jet cooking the starch. See col. 8, line 64 – col. 13, line 21.

Eskins fails to teach cationic starch.

Van Soest teaches that cationic starch is well known encapsulating material for hydrophobic or water insoluble solid active ingredients. See col. 1, line 36 – col. 2, line 11.

Fletcher et al. teach viscous antiperspirant aqueous emulsions comprising amphoteric or cationic modified starch. See abstract; col. 1, line 7 – col. 35; col. 7, lines 6 – 30. The reference teaches that the compositions exhibit excellent phase stability even in the high concentrated antiperspirant salts in the solution and elevated storage temperature. See col. 2, line 53 - col. 19, line 22.

Goldemberg teaches that it is well known in cosmetic art to employ cationic modified starch to entrap and stabilize antioxidants in a cosmetic composition. See page 2, 6th full par.

Given the teaching of starch encapsulants for cosmetic ingredients in Eskins, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have looked to the prior arts such as an Soest, Fletcher, and Goldemberg for specific type of starch and used cationic starch as motivated by the teachings of these references because of the expectation of successfully producing a stable cosmetic composition.

B. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eskins, Van Soest, Fletcher, and Goldemberg as applied to claims 32-35, 39-42, and 46-48 above, and further in view of Macaulay (US 6362146 B1).

The combined references fail to teach sunscreen active ingredients.

Macaulay teaches that encapsulated sunscreens are known in the art. See col. 6, lines 4 – 25. The reference further teaches a water-based cleansing composition comprising 2, 5, and 10% of the encapsulated sunscreen actives. See Example 1; instant claims 27 and 42.

Given the teaching of the cosmetic application of the starch-encapsulated active ingredients in Eskins, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have added sunscreen actives in the active ingredients, as motivated by Macaulay, because of the expectation of successfully producing controlled-release sunscreen compositions:

C. Claims 29-31 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eskins, Soest, Fletcher, Goldemberg, and Macaulay as applied to claims 26-28, 39-42, and 46-48 above, and further in view of Ashley ("Sunburn and Sunscreen Preparations", Poucher's Perfumes, Cosmetics, and Soaps).

The combined references fail to teach the water content in the cosmetic compositions as required by the instant claims.

Ashley teaches various formulations for sunscreen and suntan preparation. See p. 434 – p. 437. Formula 4 and 6 shows cream composition having about 40 and 20 % of water by weight, respectively.

While there is no explicit teaching of using only 10 % of water as in instant claims 29 and 43, it must be noted that differences in concentration generally will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in Ashley, examiner views that one having ordinary skill in the art would have discovered the optimum or workable ranges by routine experimentation.

Given the general teaching of sunscreen composition in the combined references, the skilled artisan would have been further motivated to look to the prior art such as Ashley for examples of the conventional sunscreen formulations.

(10) Response to Argument

A. Claims 32-35, 39-42, and 46-48 are properly rejected over Eskins in view of Van Soest, Fletcher, and Goldemberg.

Applicants argue that the prior arts fail to teach starch-encapsulated hydrophobic material that is “essentially non-separable in an aqueous formulation”. Specifically, applicants state that the Eskins’ non-separable starch-oil composition forms a smooth, stable dispersion when added to water, whereas the starch-encapsulated hydrophobic material of the present invention, when added to “an aqueous-based formulation”, “does not disperse into the water but rather remains non-separable as a suspension”.

However, not all “aqueous-based formulation” contains water alone. It may contain water-soluble polymers, thickeners, polyols, moisturizing agents, etc., as applicants have disclosed. See applicants’ specification, p. 16, Example 12. Thus, the dispersibility of the prior art in water alone and the present invention’s non-separable nature in “an aqueous formulation” is not an adequate comparison. Moreover, the “smooth and stable” dispersion of the Eskins non-separable oil-starch particles in water does not in any way indicate that the hydrophobic actives are separated from the starch in water. The composition is described as “non-separable”, which means that the oil remains intact in the starch particles.

Applicants assert that Eskins make admission that the prior art is “not directed towards the type of product that the present invention provides”. In col. 8, lines 51 –

53, Eskins makes the distinction of its invention from the previously known starch encapsulated oil on the basis of the oil droplet size: the reference describes that previously starch encapsulation of oil with "relatively large drops of oil" have been made. The reference teaches in col. 8, lines 34 – 36 that the Eskins starch particles contain micron-sized droplets of oil that are uniformly **entrapped** within a starch or starch-water matrix. Examiner asserts that droplets of oils that are **entrapped** within a starch matrix are equivalent to **encapsulated** oils. The only difference here is the size of the oil droplets, which is not a claim limitation in the present application.

Even if the Eskins composition were somehow different from starch-encapsulated oil, which examiner views is not the case here, the reference still would not teach away from the present invention. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. See In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." See In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). In this case, Eskins teaches that starch-encapsulation of oils had been known. The present invention does not become unobvious merely because the prior art describes it as a nonpreferred embodiment.

Applicants argue "it is specious at best to state that one skilled in the art, having Eskins before him, would be motivated to look to Van Soest for the use of its cationic starches granules in the jet-cooking process of Eskins to form the solubilized or cooked-out starch constituent of Eskins". Applicants' arguments are not viewed persuasive

because Van Soest teaches that granular starches are solubilized by chemicals. See Van Soest, col. 1, line 59 – col. 2, line 11. Eskins in fact teaches using modified starches, and Van Soest teaches, “granular starch is also considered chemically or physically modified starch of which most of the original shape and size is maintained during modification”. There is no teaching or suggestion in either reference that the Van Soest modified, cationic granular starch should not be used to make a starch-encapsulated hydrophobic active ingredient. The Eskins reference also states, “modified starch does not have the sticky, gummy properties of unmodified starch and also functions as an emulsion stabilizer”. See Eskins col. 3, lines 55 – 65 (referring to the Hermansson patent). Thus the references provide ample motivation for a skilled artisan to use modified starch such as the modified cationic starch in Van Soest to stabilize an aqueous composition containing hydrophobic materials. The presence of surfactants in the Van Soest composition does not negate the teaching of the Eskins that modified starches stabilize emulsifier-free emulsion. Thus applicants’ assertion that there is no motivation to use cationic starch to make a starch-encapsulated oil in view of Eskins and Van Soest is unpersuasive.

Applicants assert that Fletcher teaches away from using cationic starch in an emulsifier-free composition because the Fletcher emulsion, which contains cationic starch, uses emulsifiers. The argument is not persuasive because Fletcher is in fact cited to show that the phase stabilizing property of cationic modified starch would be the motivating factor for a skilled artisan to select that material to stabilize an aqueous composition containing hydrophobic actives.

Applicants further argue that Goldemberg is limited to using cationic starch to encapsulate hydrophilic active ingredients. Examiner notes that encapsulating hydrophobic active compounds with modified starches is taught by the Eskins and Van Soest references.

B. Claims 26-28 are properly rejected over Eskins in view of Van Soest Fletcher and Goldemberg, and further in view of Macaulary.

Applicants assert that Eskins provide no motivation to a skilled artisan to seek use of its starch-oil compositions for encapsulation of sunscreen actives. The argument is unpersuasive, as the reference clearly teaches that the invention is applicable in "health care product field" as "carriers or vehicles" of "pharmaceutical, cosmetic and personal care product formulations". See Eskins, col. 11, lines 60-67. Specifically, the reference teaches applying the invention to hand and body lotions and creams, shampoos, sun tan lotions, and the like. See *Id.* Van Soest also teaches applying the invention to encapsulate pharmaceutical and cosmetic active agents. See col. 4, lines 33-35. Compositions comprising encapsulated sunscreen actives as taught by Macaulay are personal care, cosmetic products. Thus it would have been obvious to one of ordinary skill in personal care, cosmetic art to combine the references to make the present invention.

Applicants' argument that that the combination of the references would only result in dispersion of sunscreen actives is unpersuasive. Eskins teaches that oil and starch are "non-separable" in an aqueous composition, and it is the oil-starch composition, and not the oil active alone, that is dispersed in the aqueous phase.

C. Claims 29-31, 36-38, and 43-45 are properly rejected over Eskins in view of Van Soest, Fletcher, Goldemberg and Macaulay, and further in view of Ashley.

Applicants argue that the rejection is not proper because the Ashley reference fails to teach aqueous cosmetic formulations containing starch encapsulated ingredients. The argument is unpersuasive, since the rejection is based on the combined teachings of the references. Examiner have provided sufficient evidences to show that aqueous cosmetic composition comprising starch encapsulated materials are well known in cosmetic art, as seen in Eskins and Van Soest. Adjusting the water content of an aqueous sunscreen composition as applicants have done is within the skill of the art, as supported by Ashley.

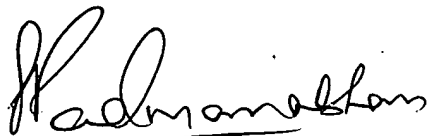
For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Gina C. Yu



Conferees:



**SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER**

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PRIMARY EXAMINER**

